K090621

FLOWCARDIA, INC.

5) 510(k) Summary

This summary of 510(k) information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21CFR807.92.

510(k) Number _____

JUN 19 2009

Applicant Information

Date Prepared:	**March 6, 2009**
Name and Address:	**FlowCardia, Inc.** **745 N. Pastoria Avenue** **Sunnyvale, CA 94085** **Ph: (408) 617-0352**
Contact Person:	**Dustin Michaels, Vice President of CR/QA/RA** **Ph: (408) 617-0352 x302** **Fax: (408) 617-9198**

Device Information

Trade / Device Name:	The FlowCardia FlowMate Injector
Regulation Number:	21 CFR 880.1650
Device Classification Name:	Angiographic injector and syringe
Regulatory Class:	II
Product Code:	DXT

Since the FlowCardia FlowMate Injector is intended to be an accessory to the FlowCardia CROSSER System, the device information of the CROSSER is referenced below:

Trade / Device Name:	The CROSSER System
Regulation Number:	21 CFR 870.1250
Device Classification Name:	Percutaneous Catheter
Regulatory Class:	II
Product Code:	DQY
510(k) numbers:	K062868, K072776, K080765

Predicate Device

The Mark V Plus Angiographic Injection System manufactured by Medrad, Inc. (K903390)

Device Description

The FlowMate Injector is a sterile saline injector intended to be used as an accessory to the CROSSER CTO Recanalization System. The CROSSER System consists of a Generator, footswitch, and disposable catheter. The FlowMate Injector is designed to infuse saline at a rate of 0.3ml/sec (18 ml/min) at a maximum back pressure of 200 PSI. The FlowMate Injector is compatible for use with a 150ml disposable sterile syringe and is operated by a footswitch. A jumper cable is supplied with the FlowMate Injector to allow connection to the CROSSER System Generator. The FlowMate Injector is programmed to first start the Injector, and then the CROSSER System Generator each time the footswitch is depressed.

Technological Characteristics

The FlowCardia FlowMate Injector is substantially equivalent to the predicate device. The predicate and FlowCardia FlowMate Injector are substantially equivalent with respect to meeting performance specifications and meeting electrical and safety standards. Both devices are intended for infusion using a 150 ml disposable syringe. In addition, both the FlowMate Injector and the predicate may be used to control other electromechanical equipment (the FlowCardia CROSSER System Generator and radiographic imaging systems, respectively).

Physical Test Data

Design analysis and comparative bench testing were conducted according to the relevant guidance documents to demonstrate that the FlowCardia FlowMate Injector met the acceptance criteria and performed similarly to the predicate device. The following functional and safety tests were performed: design validation, installation and set-up verification, output volume verification, alarm and safety function verification, electrical safety and electromagnetic compatibility, life cycle testing and CROSSER System Generator integration verification.

Conclusion

Based upon technological and physical comparisons the FlowCardia FlowMate Injector is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 19 2009

FlowCardia, Inc.
c/o Mr. Dustin Michaels
Vice President, Clinical, Quality & Regulatory Affairs
745 North Pastoria Ave.
Sunnyvale, CA 94085

Re: K090621
Trade/Device Name: FlowMate Injector
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector and Syringe
Regulatory Class: Class II
Product Code: DXT
Dated: June 12, 2009
Received: June 16, 2009

Dear Mr. Michaels:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vickers

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K090621

Device Name: FlowCardia FlowMate Injector

Indications for Use:

The FlowCardia FlowMate Injector is intended for use as a sterile saline injector for use as an accessory to the FlowCardia CROSSER CTO Recanalization System.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachey

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K090621